Renal Denervation

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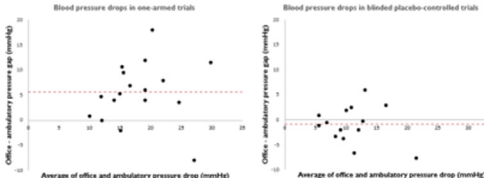
TCT-486

What blood pressure reduction should we expect from renal denervation? Insights from office versus ambulatory pressure reductions in uncontrolled and blinded placebo-controlled drug trials of 4,121 patients

James P. Howard[1], Darrel P. Francis[1], Alexandra N. Nowbar[1]
[1]Imperial College London, London, United Kingdom

Background: Trials of renal denervation report drops of ~30mmHg in office systolic blood pressure, yet reductions in ambulatory pressures appear to be ~3-fold smaller. It has been claimed this disparity is seen in antihypertensive drug trials. We examine this office-ambulatory discrepancy though meta-analysis of drug trials reporting office and ambulatory pressures.
Methods: We tested the hypothesis that office pressure drops overestimate ambulatory drops by meta-analysis of both one-armed and double-blinded placebo-controlled drug trials.
Results: DRUG TRIALS: 31 drug trials enrolling 4,121 patients met the criteria. Office blood pressure drop per unit ambulatory pressure drop was 1.46 (95% CI 1.23 to 1.68) in uncontrolled trials, but only 0.96 (95% CI 0.81 to 1.12) for blinded placebo-controlled trials. DENERVATION: 23 trials enrolling 720 patients were analysed. Office pressure drops were 26.7 mmHg versus controls in open label trials. Ambulatory pressure drops averaged 15.7 mmHg. No randomized blinded results are available.



Conclusions: In drug trials only unblinded uncontrolled studies demonstrate office pressure drops to be larger than ambulatory drops. The office-ambulatory pressure drop discrepancy in renal denervation trials may therefore be absent from future double-blinded trials. Persistence of the discrepancy would only be possible if renal denervation managed to abolish the alerting response, or 'white coat effect', implying that the alerting response is mediated by the renal sympathetic nerves.

TCT-487

Renal Sympathetic Denervation for Resistant Hypertension in the Real World Clinical Practice: Results of the Symplicity Venezuelan Registry

Humberto S. Casal[1], Carlos A. Collet[2], Nusen Beer[1], Bruno Burger[3], Victor Bellera[4], Carlos Caldera[5], Humberto Casal Heredia[1], Jose Condado[6], Roberto C. Correa[7], Enrique Fermin[8], Carlos Galan[9], Mauro Herrera[5], Pedro Hidalgo[10], Carlos E. Leon[11], Juan Simon Muñoz[12], Cesar Ochoa[13], Aguiar Pedro[14], Victor Rodriguez[15], Jose Miguel Torres[16], Gabriel Varnagy[1], Jose Robinson Vasquez[17]
[1]Hospital de Clinicas Caracas, Caracas, Venezuela, [2]Clinica El Avila, Caracas, Venezuela, [3]CMDLT, Caracas, Venezuela, [4]La Vina, valencia, Venezuela, [5]Instituto Urologico, Caracas, Venezuela, [6]centro medico de caracas, Caracas, Venezuela, [7]CentroMedicoCaracas, Caracas, Venezuela, [8]Hospital de Clinicas Caracas, caracas, Venezuela, [9]Hospital Clinico Universitario Maracaibo, maracaibo, Venezuela, [10]Clinica Amado, Maracaibo, Venezuela, [11]Centro Oncologico, Barquisimeto, Venezuela, [12]La Floresta, Caracas, Venezuela, [13]Hospital de Clinicas Caracas, Caracas, DF, [14]La Floresta, caracas, Venezuela, [15]HUC, Caracas, Venezuela, [16]Clinica Santa Sofia, Caracas, Venezuela, [17]hospital de Clinicas Caracas, caracas, Miranda

Background: Catheter-based renal denervation (RDN) had shown to be an effective treatment to control blood pressure (BP) in patients with resistant hypertension. In the Symplicity HTA-2 randomized controlled trial, RDN lowered systolic blood pressure by 32 ± 23 mmHg. In addition, radiofrequency (RF) ablation of renal arteries reduces sympathetic activity reducing left ventricular mass and insulin resistance. However, the efficacy of this novel procedure in the real world clinical practice is still unknown.
Methods: Prospective, multicenter, observational registry of consecutive patients submitted to RDN at 20 centers in Venezuela between February and December 2012. We included patients with resistant hypertension defined as systolic BP > 160 mmHg despite taking three or more antihypertensive drugs with normal renal function (estimated glomerular filtration rate > 45 ml/min/1.73 mts2). The primary end-point was reduction in systolic BP at 1 and 6 months follow-up, the secondary end-point was any adverse event after the procedure.
Results: One hundred patients were included for this analysis; mean age was 54.9 ± 11, 46% were females, 49% caucasians and 33% diabetics. Pre-procedural office BP was 173/99 mmHg (SD 20/14), the mean number of anti-hypertertensive medications was 4.3 (85% diuretics with 23% aldosterone antagonist). Regarding procedural characteristics 9.9 ± 1.9 RF ablations were done per patient, with a mean impedance reduction of -13.8%. At 30 days office BP reduction was –33/17 mmHg (SD 22/15 p=0.002) and at 6 months (n=75) –32/15 mmHg (p=0.004). One intraprocedural renal artery dissection occurred before radiofrequency energy delivery that required no additional treatment and there were no adverse events during follow-up.
Conclusions: Catheter-based RDN effectively reduces BP in the real world scenario with this benefits maintain at 6 months follow-up. In this preliminary experience, no major complication was observed.

TCT-488

ALSTER-BP Registry: Follow up data from 100 patients including first re-do procedures

Lukas Kaiser[1], Thomas Beister[1], Andrea Wiese[1], Felix Meincke[1], Jasper von Wedel[1], Andreas Busjahn[2], Karl-Heinz Kuck[1], Martin W. Bergmann[1]
[1]Asklepios Klinik St.Georg, Hamburg, Germany, [2]HealthTwiSt GmbH, Berlin, Germany

Background: Renal denervation has gathered great impact as additional therapy option for patients suffering from resistant hypertension. Here we report results of the ALSTER-BP registry including 6 month follow up data from 93 patients that were treated with renal denervation in real world setting. Additionally 8 patients underwent a second renal denervation procedure and were followed up again.
Methods: Patients matching the established inclusion criteria for renal denervation were included in the ALSTER-BP registry (n=93) and were then treated with the Symplicity renal denervation system. The follow-up period was 6 months. 8 patients who showed no or insufficient blood pressure reduction underwent a second renal denervation procedure (re-do) 9 months after the first procedure and were followed up for another 6 months.
Results: The initial patient cohort (n=93) was divided into three groups. Early responders showed a reduction of office systolic blood pressure >10mmHg 3 months after the procedure (n=53, 57%), late responders 6 months after the procedure (n=16, 17%) and non-responders showed no significant reduction (n=24, 26%). After six months systolic blood pressure was lowered by 46±2.9 mmHg (mean±SEM, p<0.001), 31±3.4mmHg (p<0.001) and 7.1±3.3mmHg (p=0.79, ns), respectively. Ambulatory blood pressure monitoring also showed a significant reduction in the early responder group (20±5.7mmHg, p=0.002). In 5 out of 8 patients (63%) who underwent a re-do procedure office systolic blood pressure was lowered >10mmHg 6 month after the second procedure. One patient (13%) showed a significant renal artery stenosis that was treated by stent implantation 5 months after the second procedure. No other adverse side effects were observed in all other patients.
Conclusions: Renal denervation is a safe and effective therapy option even in clinical all day setting. There might be different mechanisms underlying the observed blood pressure reduction that find their expression in different response rates. The success of the re-do procedure in 63% of the patients argues in favour of current ablation techniques to not sufficiently reduce sympathetic innervation of the kidney to affect blood pressure regulation in some patients.

TCT-489

Comparison Of Arterial, Surrounding Soft Tissue And Nerve Damage With Irrigated Vs. Non-irrigated Radiofrequency Ablation

Kenichi Sakakura[1], Elena Ladich[1], Kristine Fuimaono[2], Debby Grunewald[2], Patrick O'Fallon[2], Fumiyuki Otsuka[1], Kazuyuki Yahagi[1], Frank D. Kolodgie[1], Renu Virmani[1]
[1]CVPath Institute, Inc., Gaithersburg, MD, [2]Cordis/Biosense Webster, Inc. a Johnson & Johnson Company, Irwindale, CA

Background: The effectiveness of radiofrequency (RF) ablation of renal autonomic nerves has been proven. However, long-term safety of the renal artery (RA) is of concern. The aim of our study was to determine if cooling during RF ablation preserved the RA while allowing equivalent nerve damage.
Methods: A total of 10 swine with 20 RAs were enrolled, and relegated to the irrigated 50°C (n=6), non-irrigated 65°C (n=6), non-irrigated 90°C (n=6), and control (n=2) groups. Each RA was treated with RF ablation catheter (RenLane® Renal Denervation Catheter [Cordis, Inc. Fremont, CA, USA]) with different treatment protocol as above. Animals were harvested at 10 days. RAs were serially sectioned, and stained with H&E and Movat Pentachrome.

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